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KARL STORZ ENDOSCOPY

510(k) SUMMARY

K072410

Sponsor/Submitter: Karl Storz Endoscopy – America, Inc.
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MAY – 9 2008

Contact Person: Crystal Dizol
Regulatory Affairs Specialist
Email: cdizol@ksea.com

Date of Submission: April 15, 2008

Device Trade Name: KSEA Clearvision® II Lens Irrigation System

Common Name: Suction/Irrigation Pump

Classification Name: Neurological endoscope.

Regulation Number: 21 CFR 882.1480

Product Code: GWG

Predicate Device(s): Xomed Endo-Scrub/Endo-Scrub 2 (K982594)
KSEA Clearvision® Lens Irrigation System (K013838)

Device Description: The KSEA Clearvision® II is a microprocessor-controlled pump device. The device provides irrigation to clean the objective lens of the scope and removes residual solution on the lens. It is used in conjunction with an irrigation sheath.

Indications for Use: The KSEA Clearvision® II is a lens irrigation system for cleaning the distal lens of the telescope and maintaining clear visualization without removing the scope from the surgical site during endoscopic neurosurgical procedures using an endonasal approach.

Technological Characteristics: The KSEA Clearvision® II is a microprocessor-controlled pump with a fixed flow rate and adjustable reverse flow intervals. The KSEA Clearvision® II is activated by depressing the footswitch pedal and performs a self-diagnostic check during its power up, in addition to monitoring current and device temperature during operation.

Summary of Substantial Equivalence: The KSEA Clearvision® II is substantially equivalent to the predicate device since the basic features, design, and intended uses are similar. The minor differences between the KSEA Clearvision® II and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function, or intended use of the devices. Refer to the attached substantial equivalence chart.

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Substantial Equivalence Table for KSEA Clearvision® II Lens Irrigation System

Device	KSEA Clearvision® II Lens Irrigation System	KSEA Clearvision® Lens Irrigation System (K013838)	Xomed Endo-Scrub/ Endo-Scrub 2 (K982594)
Type of Pump	Microprocessor controlled	Same	Same
Function	Irrigation and reverse flow with adjustable flow intervals	Same	Irrigation and reverse flow with adjustable cycles
Controls	Foot pedal	Same	Same
Pump Console Dimensions (w x h x d)	203 mm x 101 mm x 142 mm	203 mm x 101 mm x 130 mm	Not available
Pump Console Weight	1.5 kg	Same	Not available
Details	Reusable irrigation sheath; use with 2.7- or 4.0-mm rigid telescope and disposable tubing set	Reusable irrigation sheath; use with 2.7- or 4.0-mm rigid telescope and reusable or disposable tubing set	Disposable irrigation sheath; use with 2.7- or 4.0-mm rigid telescope and disposable tubing set
Safety Features	IEC 60601-1; IEC 60601-1-2; CE; power-up test; operating test; UL 2601.1; CAN/CSA C22.2 No. 601.1-M90	IEC 601-1; IEC 60601-1-2; CE; power-up test; operating test	IEC 60601-1-1; IEC 60601-1-2; CE
Intended Use	Lens cleaning during endoscopic neurosurgery with endonasal approach.	Lens cleaning during endoscopic sinus surgery.	Lens cleaning during endoscopic sinus surgery.

K053

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Karl Storz Endoscopy-America, Inc.
% Ms. Crystal K. Dizol
Regulatory Affairs Specialist
600 Corporate Pointe, 5th Floor
Culver City, California 90230-7600

Re: K072410
Trade/Device Name: KSEA Clearvision® II Lens Irrigation System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: April 15, 2008
Received: April 22, 2008

Dear Ms. Dizol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072410

Device Name: KSEA Clearvision® II Lens Irrigation System

Indications for Use: The KSEA Clearvision II is a lens irrigation system for cleaning the distal lens of the telescope and maintaining clear visualization without removing the scope from the surgical site during endoscopic neurosurgical procedures using an endonasal approach.

Prescription Use: ___X___ AND/OR Over-The-Counter Use:_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mam

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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